

TDMS No. 88148 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/SD

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

3,3',4,4'-Tetrachloroazobenzene

CAS Number: 14047-09-7

Date Report Requested: 06/10/2008

Time Report Requested: 07:37:02

First Dose M/F: 01/29/03 / 01/30/03

Lab: BAT

F1_R8

C Number: C88148C
Lock Date: 09/22/2005
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.0.0

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SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Accidentally Killed			1	
Dosing Accident	1			1
Moribund Sacrifice	10	12	14	14
Natural Death	11	29	31	33
Survivors				
Terminal Sacrifice	28	9	4	2
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Muscularis, Inflammation		1 (2%)		
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Inflammation			1 (2%)	
Necrosis				1 (2%)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Inflammation				1 (2%)
Parasite Metazoan	6 (12%)	6 (12%)	3 (6%)	5 (10%)
Thrombosis				1 (2%)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Inflammation				1 (2%)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Fibrosis				1 (2%)
Necrosis			1 (2%)	1 (2%)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Dysplasia			1 (2%)	
Fibrosis			1 (2%)	
Inflammation			1 (2%)	
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Necrosis			1 (2%)	
Liver	(50)	(50)	(50)	(50)
Angiectasis	2 (4%)	1 (2%)	1 (2%)	
Basophilic Focus	3 (6%)	1 (2%)	5 (10%)	2 (4%)
Cholangiofibrosis	1 (2%)	3 (6%)	2 (4%)	
Clear Cell Focus	32 (64%)	12 (24%)	8 (16%)	4 (8%)
Congestion		1 (2%)		
Degeneration, Cystic	2 (4%)		1 (2%)	1 (2%)
Eosinophilic Focus	3 (6%)	9 (18%)	4 (8%)	12 (24%)
Fatty Change, Focal	1 (2%)	2 (4%)	7 (14%)	3 (6%)

a - Number of animals examined microscopically at site and number of animals with lesion

SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Fatty Change, Diffuse	3 (6%)	9 (18%)	18 (36%)	34 (68%)
Fibrosis		1 (2%)		4 (8%)
Hematopoietic Cell Proliferation	5 (10%)	40 (80%)	37 (74%)	30 (60%)
Hepatodiaphragmatic Nodule		2 (4%)	1 (2%)	
Hyperplasia, Nodular		1 (2%)	1 (2%)	3 (6%)
Inflammation, Granulomatous			1 (2%)	
Inflammation, Chronic Active	40 (80%)	37 (74%)	30 (60%)	28 (56%)
Mixed Cell Focus	7 (14%)	3 (6%)	3 (6%)	1 (2%)
Necrosis	1 (2%)	7 (14%)	18 (36%)	21 (42%)
Pigmentation	1 (2%)	4 (8%)	5 (10%)	6 (12%)
Toxic Hepatopathy			5 (10%)	8 (16%)
Bile Duct, Cyst			1 (2%)	4 (8%)
Bile Duct, Dilatation		1 (2%)	3 (6%)	
Bile Duct, Fibrosis	10 (20%)	3 (6%)	1 (2%)	3 (6%)
Bile Duct, Hyperplasia	34 (68%)	38 (76%)	36 (72%)	29 (58%)
Bile Duct, Metaplasia				1 (2%)
Centrilobular, Degeneration		10 (20%)	23 (46%)	24 (48%)
Centrilobular, Fatty Change				1 (2%)
Hepatocyte, Hypertrophy		6 (12%)	11 (22%)	22 (44%)
Hepatocyte, Multinucleated			1 (2%)	3 (6%)
Oval Cell, Hyperplasia		4 (8%)	8 (16%)	5 (10%)
Mesentery	(0)	(0)	(0)	(1)
Oral Mucosa	(50)	(50)	(50)	(50)
Gingival, Hyperplasia, Cystic Keratinizing		4 (8%)	18 (36%)	11 (22%)
Gingival, Hyperplasia, Squamous	2 (4%)	21 (42%)	24 (48%)	31 (62%)
Pancreas	(50)	(49)	(50)	(50)
Atrophy	4 (8%)	13 (27%)	10 (20%)	10 (20%)
Fibrosis	1 (2%)			
Inflammation	1 (2%)	7 (14%)	7 (14%)	3 (6%)
Acinus, Hyperplasia	8 (16%)	2 (4%)	2 (4%)	
Acinus, Necrosis		1 (2%)		
Acinus, Vacuolization Cytoplasmic		16 (33%)	30 (60%)	13 (26%)
Salivary Glands	(50)	(50)	(49)	(50)
Atrophy		1 (2%)		3 (6%)
Cyst			1 (2%)	
Fibrosis				1 (2%)
Hyperplasia	1 (2%)			
Inflammation	1 (2%)			
Stomach, Forestomach	(50)	(50)	(50)	(50)
Cyst				1 (2%)
Inflammation	5 (10%)	2 (4%)	2 (4%)	3 (6%)
Mineralization	2 (4%)		1 (2%)	
Necrosis		3 (6%)	1 (2%)	1 (2%)
Epithelium, Hyperplasia	8 (16%)	36 (72%)	44 (88%)	45 (90%)
Stomach, Glandular	(50)	(50)	(50)	(50)
Inflammation	2 (4%)		1 (2%)	

SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Mineralization	3 (6%)	2 (4%)	2 (4%)	1 (2%)
Necrosis			1 (2%)	
Tooth	(50)	(50)	(50)	(50)
Peridental Tissue, Inflammation	11 (22%)	12 (24%)	19 (38%)	16 (32%)

CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Inflammation	21 (42%)	29 (58%)	30 (60%)	29 (58%)
Mineralization	5 (10%)	1 (2%)	4 (8%)	3 (6%)
Aorta, Intima, Hyperplasia		1 (2%)		
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	47 (94%)	48 (96%)	45 (90%)	40 (80%)
Inflammation	1 (2%)		2 (4%)	1 (2%)
Mineralization	5 (10%)		1 (2%)	1 (2%)
Necrosis				2 (4%)
Thrombosis		4 (8%)	2 (4%)	4 (8%)
Endocardium, Hyperplasia		1 (2%)		

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Angiectasis	1 (2%)		1 (2%)	
Degeneration	4 (8%)	14 (28%)	14 (28%)	9 (18%)
Hypertrophy	33 (66%)	24 (48%)	11 (22%)	17 (34%)
Infiltration Cellular, Mononuclear Cell		1 (2%)		
Necrosis		2 (4%)	4 (8%)	13 (26%)
Vacuolization Cytoplasmic	20 (40%)	29 (58%)	31 (62%)	25 (50%)
Zona Fasciculata, Hyperplasia	14 (28%)	22 (44%)	19 (38%)	21 (42%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Hyperplasia	10 (20%)	8 (16%)	5 (10%)	6 (12%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia	1 (2%)			1 (2%)
Parathyroid Gland	(43)	(48)	(44)	(44)
Hyperplasia	8 (19%)	9 (19%)	6 (14%)	2 (5%)
Pituitary Gland	(50)	(50)	(50)	(49)
Angiectasis		1 (2%)		
Hemorrhage				1 (2%)
Hyperplasia	1 (2%)			
Necrosis				2 (4%)
Pars Distalis, Hyperplasia	18 (36%)	10 (20%)	13 (26%)	10 (20%)
Pars Intermedia, Necrosis		1 (2%)		
Rathke's Cleft, Hyperplasia	1 (2%)			
Thyroid Gland	(50)	(50)	(50)	(50)

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SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Angiectasis		1 (2%)		
Atrophy			1 (2%)	
Fibrosis				1 (2%)
Inflammation		3 (6%)	9 (18%)	14 (28%)
C-cell, Hyperplasia	7 (14%)	1 (2%)	2 (4%)	1 (2%)
Follicle, Cyst	1 (2%)			
Follicular Cell, Hyperplasia		2 (4%)	10 (20%)	12 (24%)
Follicular Cell, Hypertrophy	2 (4%)	2 (4%)	6 (12%)	6 (12%)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Coagulating Gland	(50)	(50)	(50)	(49)
Inflammation	1 (2%)	3 (6%)	2 (4%)	4 (8%)
Metaplasia, Squamous				1 (2%)
Epididymis	(50)	(50)	(50)	(50)
Granuloma Sperm		1 (2%)	3 (6%)	2 (4%)
Inflammation	3 (6%)			
Preputial Gland	(50)	(50)	(50)	(49)
Ectasia	1 (2%)			
Hyperplasia, Squamous	2 (4%)	3 (6%)	1 (2%)	4 (8%)
Inflammation	5 (10%)			1 (2%)
Prostate	(50)	(50)	(50)	(50)
Inflammation	13 (26%)	12 (24%)	7 (14%)	16 (32%)
Epithelium, Hyperplasia	12 (24%)	4 (8%)	3 (6%)	2 (4%)
Seminal Vesicle	(50)	(50)	(50)	(50)
Hyperplasia				2 (4%)
Inflammation		2 (4%)	1 (2%)	4 (8%)
Metaplasia, Squamous				3 (6%)
Mineralization	1 (2%)			
Testes	(50)	(50)	(50)	(50)
Inflammation	1 (2%)	1 (2%)		1 (2%)
Necrosis		2 (4%)	1 (2%)	3 (6%)
Thrombosis		1 (2%)		
Germinal Epithelium, Degeneration	15 (30%)	16 (32%)	18 (36%)	21 (42%)
Germinal Epithelium, Mineralization	3 (6%)	3 (6%)	3 (6%)	4 (8%)
Interstitial Cell, Hyperplasia		1 (2%)		1 (2%)

HEMATOPOIETIC SYSTEM

SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Bone Marrow	(50)	(50)	(49)	(50)
Atrophy		1 (2%)	2 (4%)	2 (4%)
Hyperplasia	12 (24%)	7 (14%)	21 (43%)	19 (38%)
Necrosis				1 (2%)
Lymph Node	(38)	(28)	(29)	(41)
Pigmentation		1 (4%)		
Deep Cervical, Atrophy				1 (2%)
Deep Cervical, Ectasia				1 (2%)
Deep Cervical, Hematopoietic Cell Proliferation	1 (3%)			
Mediastinal, Atrophy	2 (5%)			1 (2%)
Mediastinal, Ectasia		1 (4%)		1 (2%)
Mediastinal, Hemorrhage			1 (3%)	1 (2%)
Mediastinal, Hyperplasia, Lymphoid		1 (4%)		3 (7%)
Mediastinal, Infiltration Cellular, Histiocyte		1 (4%)		
Pancreatic, Hyperplasia, Lymphoid		1 (4%)		
Lymph Node, Mandibular	(49)	(50)	(49)	(50)
Atrophy	5 (10%)	1 (2%)		7 (14%)
Congestion		1 (2%)		
Ectasia		1 (2%)		
Hyperplasia, Lymphoid	2 (4%)	6 (12%)	1 (2%)	2 (4%)
Infiltration Cellular, Histiocyte			1 (2%)	
Necrosis			2 (4%)	
Pigmentation	1 (2%)			2 (4%)
Lymph Node, Mesenteric	(50)	(48)	(50)	(50)
Atrophy		1 (2%)	1 (2%)	5 (10%)
Hyperplasia, Lymphoid		2 (4%)	2 (4%)	
Inflammation, Granulomatous				1 (2%)
Pigmentation	1 (2%)	24 (50%)	25 (50%)	20 (40%)
Spleen	(50)	(50)	(50)	(50)
Atrophy	1 (2%)			
Congestion			1 (2%)	
Hematopoietic Cell Proliferation	38 (76%)	48 (96%)	44 (88%)	41 (82%)
Pigmentation	38 (76%)	39 (78%)	40 (80%)	35 (70%)
Thrombosis	1 (2%)			
Lymphoid Follicle, Atrophy	5 (10%)	4 (8%)	5 (10%)	12 (24%)
Thymus	(48)	(48)	(46)	(48)
Atrophy	45 (94%)	47 (98%)	44 (96%)	47 (98%)
Inflammation				1 (2%)
Thymocyte, Hyperplasia	1 (2%)			
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Inflammation				1 (2%)

SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Mineralization	1 (2%)			
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion	2 (4%)	3 (6%)	2 (4%)	4 (8%)
Hyperplasia	2 (4%)		1 (2%)	
Inflammation	1 (2%)	1 (2%)	2 (4%)	2 (4%)
Ulcer		1 (2%)	1 (2%)	1 (2%)
Hair Follicle, Hyperplasia		1 (2%)		
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Hyperostosis				1 (2%)
Tendon, Inflammation			1 (2%)	1 (2%)
Skeletal Muscle	(0)	(0)	(2)	(0)
Hemorrhage			1 (50%)	
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Edema		1 (2%)		
Gliosis		2 (4%)		
Hemorrhage	1 (2%)			2 (4%)
Necrosis		4 (8%)	1 (2%)	3 (6%)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Congestion	1 (2%)	2 (4%)		
Fibrosis		1 (2%)		
Foreign Body	1 (2%)			
Hemorrhage	1 (2%)			
Inflammation, Granulomatous	7 (14%)	1 (2%)	2 (4%)	5 (10%)
Inflammation, Chronic Active	6 (12%)	6 (12%)	6 (12%)	5 (10%)
Mineralization	1 (2%)			
Necrosis	1 (2%)	1 (2%)		
Pigmentation	3 (6%)	16 (32%)	12 (24%)	16 (32%)
Alveolar Epithelium, Hyperplasia	2 (4%)	3 (6%)		2 (4%)
Alveolar Epithelium, Metaplasia, Bronchiolar	1 (2%)	33 (66%)	32 (64%)	34 (68%)
Alveolar Epithelium, Metaplasia, Squamous		14 (28%)	22 (44%)	22 (44%)
Alveolus, Infiltration Cellular, Histiocyte	23 (46%)	34 (68%)	35 (70%)	35 (70%)
Smooth Muscle, Hyperplasia, Focal	1 (2%)			
Nose	(50)	(50)	(50)	(50)
Foreign Body	2 (4%)			

SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Inflammation Nasolacrimal Duct, Hyperplasia	10 (20%)	5 (10%)	9 (18%) 1 (2%)	9 (18%)
SPECIAL SENSES SYSTEM				
Ear	(0)	(1)	(0)	(0)
External Ear, Hyperplasia, Squamous		1 (100%)		
Eye	(48)	(50)	(50)	(50)
Anterior Chamber, Inflammation	1 (2%)	2 (4%)	1 (2%)	1 (2%)
Cornea, Degeneration		1 (2%)		
Cornea, Hyperplasia, Squamous	1 (2%)			
Cornea, Inflammation	3 (6%)	12 (24%)	5 (10%)	2 (4%)
Cornea, Mineralization		1 (2%)		
Lens, Cataract			1 (2%)	
Optic Nerve, Infiltration Cellular, Mononuclear Cell			1 (2%)	
Retina, Atrophy				1 (2%)
Retina, Degeneration	1 (2%)	1 (2%)	6 (12%)	2 (4%)
Harderian Gland	(50)	(50)	(50)	(50)
Atrophy	1 (2%)			1 (2%)
Inflammation		1 (2%)		
Lacrimal Gland	(0)	(1)	(0)	(0)
Cytoplasmic Alteration		1 (100%)		
Zymbal's Gland	(1)	(0)	(1)	(0)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Mineralization	22 (44%)	20 (40%)	24 (48%)	24 (48%)
Nephropathy	50 (100%)	50 (100%)	47 (94%)	48 (96%)
Cortex, Cyst	2 (4%)	3 (6%)	1 (2%)	2 (4%)
Pelvis, Dilatation				1 (2%)
Pelvis, Inflammation	1 (2%)	2 (4%)		2 (4%)
Pelvis, Transitional Epithelium, Hyperplasia	1 (2%)	1 (2%)	1 (2%)	1 (2%)
Renal Tubule, Hyperplasia, Atypical			1 (2%)	
Transitional Epithelium, Hyperplasia	1 (2%)			
Ureter	(41)	(31)	(42)	(49)
Transitional Epithelium, Hyperplasia				3 (6%)
Urethra	(50)	(50)	(50)	(50)
Transitional Epithelium, Hyperplasia				2 (4%)
Urinary Bladder	(50)	(50)	(50)	(50)
Inflammation	1 (2%)	1 (2%)	2 (4%)	

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SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
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*** END OF MALE ***

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SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Accidentally Killed			1	
Dosing Accident	1		1	
Moribund Sacrifice	15	12	10	11
Natural Death	9	8	19	22
Survivors				
Moribund Sacrifice			1	
Terminal Sacrifice	25	30	18	17
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Intestine Large, Cecum	(50)	(48)	(50)	(49)
Necrosis				1 (2%)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Parasite Metazoan	6 (12%)	2 (4%)		3 (6%)
Intestine Small, Duodenum	(50)	(50)	(50)	(49)
Intestine Small, Ileum	(50)	(49)	(49)	(49)
Intestine Small, Jejunum	(50)	(49)	(50)	(49)
Liver	(50)	(50)	(49)	(49)
Angiectasis		4 (8%)	3 (6%)	5 (10%)
Basophilic Focus	14 (28%)	10 (20%)	9 (18%)	7 (14%)
Cholangiofibrosis		1 (2%)		11 (22%)
Clear Cell Focus	13 (26%)	22 (44%)	9 (18%)	7 (14%)
Degeneration, Cystic		2 (4%)	3 (6%)	
Eosinophilic Focus	3 (6%)	27 (54%)	31 (63%)	38 (78%)
Fatty Change, Focal	2 (4%)	2 (4%)	2 (4%)	9 (18%)
Fatty Change, Diffuse		3 (6%)	10 (20%)	10 (20%)
Fibrosis	1 (2%)		2 (4%)	6 (12%)
Hematopoietic Cell Proliferation	28 (56%)	42 (84%)	32 (65%)	37 (76%)
Hepatodiaphragmatic Nodule	1 (2%)		1 (2%)	1 (2%)
Hyperplasia, Nodular	1 (2%)	3 (6%)	11 (22%)	22 (45%)
Inflammation, Chronic Active	29 (58%)	29 (58%)	32 (65%)	30 (61%)
Mixed Cell Focus	6 (12%)	16 (32%)	14 (29%)	16 (33%)
Necrosis	3 (6%)	6 (12%)	10 (20%)	10 (20%)
Necrosis, Focal				2 (4%)
Pigmentation	1 (2%)	17 (34%)	32 (65%)	40 (82%)
Thrombosis	1 (2%)		1 (2%)	
Toxic Hepatopathy		4 (8%)	14 (29%)	25 (51%)
Bile Duct, Cyst	3 (6%)	4 (8%)	5 (10%)	12 (24%)

SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Bile Duct, Fibrosis	1 (2%)	1 (2%)	5 (10%)	1 (2%)
Bile Duct, Hyperplasia	12 (24%)	26 (52%)	29 (59%)	38 (78%)
Centrilobular, Degeneration	1 (2%)	2 (4%)	18 (37%)	17 (35%)
Hepatocyte, Hypertrophy	4 (8%)	33 (66%)	38 (78%)	42 (86%)
Hepatocyte, Multinucleated		2 (4%)	1 (2%)	28 (57%)
Oval Cell, Hyperplasia		7 (14%)	24 (49%)	36 (73%)
Serosa, Fibrosis		1 (2%)		
Mesentery	(3)	(2)	(1)	(3)
Thrombosis			1 (100%)	
Fat, Necrosis	1 (33%)	1 (50%)		2 (67%)
Oral Mucosa	(50)	(50)	(50)	(50)
Gingival, Hyperplasia, Cystic Keratinizing		4 (8%)	9 (18%)	13 (26%)
Gingival, Hyperplasia, Squamous		8 (16%)	24 (48%)	24 (48%)
Pancreas	(50)	(49)	(49)	(49)
Atrophy		11 (22%)	12 (24%)	13 (27%)
Inflammation	1 (2%)	1 (2%)	4 (8%)	6 (12%)
Acinus, Hyperplasia			1 (2%)	1 (2%)
Acinus, Vacuolization Cytoplasmic		27 (55%)	33 (67%)	40 (82%)
Duct, Atypia Cellular			1 (2%)	
Salivary Glands	(50)	(49)	(50)	(49)
Atrophy	1 (2%)	1 (2%)		2 (4%)
Fibrosis		1 (2%)		
Duct, Cyst				1 (2%)
Stomach, Forestomach	(50)	(49)	(50)	(49)
Cyst				2 (4%)
Inflammation	1 (2%)	3 (6%)	5 (10%)	7 (14%)
Mineralization	2 (4%)	2 (4%)	1 (2%)	
Necrosis			3 (6%)	2 (4%)
Epithelium, Hyperplasia		32 (65%)	46 (92%)	46 (94%)
Stomach, Glandular	(50)	(49)	(49)	(49)
Inflammation	1 (2%)			
Mineralization		1 (2%)	1 (2%)	
Tooth	(50)	(50)	(50)	(50)
Peridental Tissue, Inflammation	5 (10%)	10 (20%)	14 (28%)	9 (18%)

CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Inflammation	1 (2%)	10 (20%)	14 (28%)	16 (32%)
Mineralization	2 (4%)	1 (2%)	2 (4%)	1 (2%)
Thrombosis				1 (2%)
Heart	(50)	(50)	(49)	(49)
Cardiomyopathy	12 (24%)	16 (32%)	13 (27%)	24 (49%)
Dilatation				1 (2%)
Inflammation			1 (2%)	1 (2%)

SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Mineralization			1 (2%)	
Necrosis			1 (2%)	1 (2%)
Thrombosis			1 (2%)	3 (6%)
Endocardium, Hyperplasia	2 (4%)			
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(49)
Atrophy		1 (2%)	1 (2%)	
Degeneration	13 (26%)	12 (24%)	17 (34%)	16 (33%)
Hypertrophy	41 (82%)	31 (62%)	30 (60%)	30 (61%)
Inflammation				1 (2%)
Necrosis	1 (2%)		7 (14%)	5 (10%)
Thrombosis		1 (2%)	1 (2%)	1 (2%)
Vacuolization Cytoplasmic	7 (14%)	16 (32%)	13 (26%)	15 (31%)
Zona Fasciculata, Hyperplasia	14 (28%)	20 (40%)	25 (50%)	21 (43%)
Adrenal Medulla	(50)	(50)	(50)	(49)
Hyperplasia	11 (22%)	5 (10%)	3 (6%)	6 (12%)
Islets, Pancreatic	(50)	(50)	(50)	(49)
Hyperplasia				1 (2%)
Parathyroid Gland	(46)	(46)	(46)	(45)
Hyperplasia				2 (4%)
Pituitary Gland	(50)	(50)	(50)	(50)
Necrosis	1 (2%)		2 (4%)	
Pigmentation	1 (2%)			
Pars Distalis, Hyperplasia	20 (40%)	13 (26%)	12 (24%)	19 (38%)
Pars Intermedia, Hyperplasia			1 (2%)	
Thyroid Gland	(50)	(49)	(50)	(50)
Inflammation			2 (4%)	4 (8%)
C-cell, Hyperplasia	12 (24%)	5 (10%)	3 (6%)	4 (8%)
Follicle, Cyst		1 (2%)		1 (2%)
Follicular Cell, Hyperplasia		1 (2%)	3 (6%)	3 (6%)
Follicular Cell, Hypertrophy		1 (2%)	2 (4%)	4 (8%)
GENERAL BODY SYSTEM				
Peritoneum	(0)	(1)	(1)	(0)
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(50)	(50)
Cyst	5 (10%)	1 (2%)	6 (12%)	
Hyperplasia, Squamous		1 (2%)	3 (6%)	

SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Inflammation	3 (6%)			
Ovary	(50)	(50)	(50)	(50)
Cyst	12 (24%)	8 (16%)	13 (26%)	12 (24%)
Inflammation		1 (2%)	2 (4%)	5 (10%)
Necrosis				1 (2%)
Oviduct	(2)	(0)	(3)	(2)
Cyst			2 (67%)	
Fibrosis	1 (50%)			
Inflammation	2 (100%)		1 (33%)	2 (100%)
Metaplasia, Squamous	1 (50%)			
Uterus	(50)	(50)	(50)	(50)
Adenomyosis				1 (2%)
Angiectasis		1 (2%)	1 (2%)	2 (4%)
Cyst				2 (4%)
Hemorrhage			1 (2%)	1 (2%)
Hydrometra				1 (2%)
Inflammation	4 (8%)	5 (10%)	3 (6%)	3 (6%)
Endometrium, Hyperplasia, Adenomatous	1 (2%)			
Endometrium, Hyperplasia, Cystic	15 (30%)	4 (8%)	5 (10%)	6 (12%)
Endometrium, Metaplasia, Squamous	20 (40%)	28 (56%)	22 (44%)	22 (44%)
Vagina	(2)	(2)	(0)	(4)
Fibrosis				1 (25%)
Hyperplasia, Squamous				1 (25%)
Inflammation				1 (25%)
Epithelium, Atypia Cellular	1 (50%)			
Epithelium, Hyperplasia	2 (100%)	2 (100%)		1 (25%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Atrophy				1 (2%)
Hyperplasia	36 (72%)	41 (82%)	40 (80%)	45 (90%)
Myelofibrosis			1 (2%)	1 (2%)
Lymph Node	(1)	(0)	(4)	(2)
Pancreatic, Hemorrhage			1 (25%)	
Popliteal, Inflammation, Chronic Active				1 (50%)
Popliteal, Necrosis				1 (50%)
Thoracic, Hyperplasia, Lymphoid			1 (25%)	
Lymph Node, Mandibular	(50)	(49)	(49)	(49)
Atrophy				4 (8%)
Hyperplasia, Lymphoid			2 (4%)	
Infiltration Cellular, Plasma Cell	1 (2%)			
Lymph Node, Mesenteric	(50)	(49)	(50)	(49)
Atrophy			4 (8%)	6 (12%)
Atrophy, Lymphoid				2 (4%)

TDMS No. 88148 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/SD

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

3,3',4,4'-Tetrachloroazobenzene

CAS Number: 14047-09-7

Date Report Requested: 06/10/2008
 Time Report Requested: 07:37:02
 First Dose M/F: 01/29/03 / 01/30/03
 Lab: BAT

SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Pigmentation	14 (28%)	32 (65%)	32 (64%)	30 (61%)
Spleen	(50)	(50)	(49)	(49)
Accessory Spleen	1 (2%)			
Hematopoietic Cell Proliferation	41 (82%)	47 (94%)	45 (92%)	45 (92%)
Necrosis, Fibrinoid		1 (2%)		
Pigmentation	31 (62%)	44 (88%)	42 (86%)	47 (96%)
Lymphoid Follicle, Atrophy	3 (6%)	4 (8%)	8 (16%)	10 (20%)
Thymus	(50)	(50)	(47)	(50)
Atrophy	47 (94%)	49 (98%)	46 (98%)	50 (100%)
Hyperplasia, Lymphoid	1 (2%)			
Inflammation, Granulomatous				1 (2%)
Vein, Thrombosis				1 (2%)
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Dilatation		1 (2%)		
Galactocele	3 (6%)			
Hyperplasia	4 (8%)	11 (22%)	11 (22%)	4 (8%)
Inflammation				1 (2%)
Pigmentation		1 (2%)		
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion				1 (2%)
Hyperplasia, Squamous				1 (2%)
MUSCULOSKELETAL SYSTEM				
Skeletal Muscle	(2)	(1)	(0)	(0)
Inflammation		1 (100%)		
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Hemorrhage			2 (4%)	
Necrosis				1 (2%)
Peripheral Nerve	(2)	(1)	(0)	(1)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(49)	(49)
Congestion	1 (2%)			
Inflammation, Suppurative	1 (2%)			

SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Inflammation, Chronic Active	4 (8%)	5 (10%)	1 (2%)	4 (8%)
Metaplasia, Cartilagenous	1 (2%)			
Necrosis	1 (2%)	1 (2%)		
Pigmentation	1 (2%)	11 (22%)	21 (43%)	26 (53%)
Thrombosis			1 (2%)	1 (2%)
Alveolar Epithelium, Hyperplasia	5 (10%)	1 (2%)		
Alveolar Epithelium, Metaplasia, Bronchiolar		21 (42%)	26 (53%)	35 (71%)
Alveolar Epithelium, Metaplasia, Squamous	2 (4%)	4 (8%)	18 (37%)	30 (61%)
Alveolus, Infiltration Cellular, Histiocyte	36 (72%)	23 (46%)	29 (59%)	33 (67%)
Artery, Hypertrophy				1 (2%)
Serosa, Inflammation, Granulomatous			1 (2%)	
Nose	(50)	(50)	(50)	(50)
Inflammation		7 (14%)	6 (12%)	8 (16%)
Trachea	(50)	(50)	(50)	(50)
SPECIAL SENSES SYSTEM				
Ear	(0)	(0)	(1)	(0)
External Ear, Hyperplasia, Squamous			1 (100%)	
Eye	(50)	(50)	(50)	(50)
Synechia				1 (2%)
Anterior Chamber, Inflammation			1 (2%)	
Cornea, Inflammation	2 (4%)			2 (4%)
Lens, Cataract				1 (2%)
Retina, Degeneration	1 (2%)		4 (8%)	1 (2%)
Harderian Gland	(50)	(50)	(50)	(50)
Inflammation				1 (2%)
Zymbal's Gland	(0)	(1)	(0)	(0)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(49)
Accumulation, Hyaline Droplet		2 (4%)		
Casts	1 (2%)			2 (4%)
Infarct		1 (2%)	4 (8%)	2 (4%)
Inflammation, Diffuse		1 (2%)	3 (6%)	2 (4%)
Mineralization	36 (72%)	32 (64%)	28 (56%)	29 (59%)
Nephropathy	30 (60%)	39 (78%)	39 (78%)	42 (86%)
Thrombosis				1 (2%)
Cortex, Cyst		1 (2%)		1 (2%)
Papilla, Necrosis			1 (2%)	2 (4%)
Pelvis, Dilatation			2 (4%)	1 (2%)
Pelvis, Inflammation	1 (2%)	2 (4%)	1 (2%)	2 (4%)
Pelvis, Transitional Epithelium, Hyperplasia	1 (2%)	1 (2%)	2 (4%)	3 (6%)

TDMS No. 88148 - 06

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Lab: BAT

SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Renal Tubule, Hyperplasia, Atypical	1 (2%)		1 (2%)	
Renal Tubule, Necrosis			3 (6%)	3 (6%)
Urethra	(50)	(50)	(50)	(49)
Inflammation		1 (2%)		
Transitional Epithelium, Hyperplasia		1 (2%)	1 (2%)	1 (2%)
Transitional Epithelium, Metaplasia, Squamous				1 (2%)
Urinary Bladder	(50)	(50)	(50)	(50)
Inflammation		1 (2%)		1 (2%)
Metaplasia, Squamous		1 (2%)		
Transitional Epithelium, Hyperplasia	1 (2%)			

*** END OF REPORT ***